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No.

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1988

TELECTRONICS, INC. and BGS MEDICAL, INC.,

Petitioners,

– against –

UNITED STATES OF AMERICA and ZIMMER, INC.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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February 21, 1989

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QUESTIONS PRESENTED

1. Whether a prior decision of a panel of the Federal Circuit is binding precedent on a subsequent different panel of the same Circuit.

2. Whether a district court's characterization of a party's position with respect to a critical issue in a lawsuit is immune from review by the appellate court.

PARTIES TO THE PROCEEDING BELOW

United States Of America (plaintiff-appellant), Zimmer, Inc. (involuntary plaintiff-counterclaim defendant), and Telectronics, Inc. and BGS Medical, Inc. (defendants-counterclaim plaintiffs-cross-appellants) were the parties to the proceeding in the Court whose judgment is sought to be reviewed.

The following entities are affiliates and/or subsidiaries of petitioners:

Electro-Biology, Inc. (the latter company having purchased the implantable bone growth stimulator business of BGS Medical, Inc.), Biomet, Inc. (the latter company having purchased Electro-Biology, Inc.), Pacific Dunlop Limited (the latter company having purchased Telectronics, Inc. and its parent companies, Telectronics Holdings Limited and Nucleus

Limited); Telectronics Holdings Limited (a publicly traded Australian company); and Nucleus Limited (a publicly traded Australian company).

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IN THE

SUPREME COURT OF THE UNITED STATES

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NO. _____

TELECTRONICS, INC.
and BGS MEDICAL, INC.,

Petitioners,

v.

UNITED STATES OF AMERICA
and ZIMMER, INC.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Petitioners Telectronics, Inc. and BGS Medical, Inc. respectfully pray that a writ of certiorari issue to review the

judgment and opinion of The United States Court Of Appeals for the Federal Circuit entered on November 30, 1988.

OPINIONS AND ORDERS

The September 22, 1988 opinion of the United States Court Of Appeals for the Federal Circuit, affirming-in-part and reversing-in-part the decision by the United State District Court for the District of Colorado, is reported at 857 F.2d 778. It is reproduced as Appendix A to this Petition.

Petitioners filed a Petition For Rehearing With Suggestion For Rehearing In Banc on October 5, 1988. The Federal Circuit entered an Order denying the Petition For Rehearing on November 23, 1988 and this Order is reproduced as Appendix B to this Petition. Subsequently, the Federal Circuit issued a Judgment

consistent with its decision. This Judgment is reproduced as Appendix C to this Petition.

JURISDICTION

This Court has jurisdiction to review the judgment by writ of certiorari under 28 U.S.C. Section 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS

The case presents issues arising under Article 1, Section 8 of the Constitution, and the Patent Statute, Title 35 of the United States Code.

(a) Article 1, Section 8 - Congress shall have power ... To promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and inventions.

(b) 35 U.S.C. Sec. 102 - A

person shall be entitled to a patent unless ... the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof,... the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent.

(c) 35 U.S.C. Sec. 103 - A patent may not be obtained though the invention is not identically disclosed or described as set forth in Section 102 matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains....

(d) 35 U.S.C. Sec. 282 - The following shall be defenses in any action involving the ...infringement of a patent and shall be pleaded: (1) Non-infringement... (2) Invalidity of the patent or any claim in suit on any ground specified... as a condition for patentability....

STATEMENT OF THE CASE

A. Proceedings In The District Court

In 1980, respondent United States Of America (hereinafter "the government") brought an action for patent infringment of United States Patent No. 3,842,841, entitled "Constant Current Power Pack For Bone Healing and Method of Use" against petitioners Telectronics, Inc. and BGS Medical, Inc. (hereinafter "Telectronics"). The patent issued on October 22, 1974 in the names of Carl T. Brighton, Zachary B. Friedenberg and William Redka, and the government alleged

infringement of claims 1, 3, 4 and 5 thereof.*

The '841 patent is directed to a bone growth stimulator device for speeding the healing of fractures and other bone defects. Bone growth stimulators are useful in the treatment of fractures normally requiring grafting, and expedite the healing of a fracture or

---

* Claim 1 reads as follows:
A system for expediting the healing of bone fractures and bone defects in a living being comprising:
constant current source means for providing a constant value of current despite changes in load;
means for connecting said constant current means to the living being, such connection acting to produce current flow into said fracture or defect,
said connecting means including further means for application internally of said living being at the fracture or defect site,
said constant current being a selected value within a predetermined microampere range so as to promote bone formation at the fracture or bone defect site and avoid fibrous tissue formation in other areas of the living being.

bone defect by passing a low level constant direct current to the site of the fracture via a cathode placed internally at the site of the fracture. An anode must also be appropriately positioned in order to complete the circuit of the device, and this placement was the basis of Telectronics' denial of infringement.

Telectronics urged that the claims were limited to a skin anode. Since the allegedly infringing device of Telectronics included an anode placed internally, it could not come within the language of the claims.

Furthermore, the language of claim 1 of the patent recites that the claimed device "avoid[s] fibrous tissue formation", and the government interpreted this to mean that fibrous tissue induced by the current is avoided or at least minimized. Telectronics denied infringe-

ment on the additional ground that its device, because of the use of an internal anode, did not avoid or minimize fibrous tissue formation.

After a bench trial in 1986, Judge Richard P. Matsch of the United States District Court for the District of Colorado issued his opinion in the action (reproduced as Appendix D to this petition). He held that the patent was not infringed by Telectronics since the language of claim 1 of the patent is limited to a skin anode.

Regarding Telectronics' counterclaim for invalidity based on obviousness (under Section 103 of the Patent Statute), Judge Matsch, having already limited the scope of the patent claims to an external anode, found that the claimed invention would not have been obvious to one of ordinary skill in the art in light

of the teachings in the applicable prior art. He specifically said, twice, that his findings of unobviousness were based on his limiting of the claims to an external (skin) anode. Judge Matsch did not even discuss the most important pieces of prior art which Telectronics had cited during the trial, prior art showing internal anodes (which Judge Matsch held were not within the embrace of the claims in the first place). Had the Court construed the claims more broadly, to include both an internal and an external anode, then the Court might have found otherwise on obviousness. Judge Matsch made that quite clear in saying that his obviousness findings were based on his narrow claim interpretation.

B. Proceedings In The Court Of Appeals

The government then appealed to the

United States Court of Appeals for the Federal Circuit pursuant to 28 U.S.C. Section 1295. The government argued that the District Court was incorrect in construing claim 1 of the patent to be limited to an external anode.

In an opinion of the Court of Appeals for the Federal Circuit dated September 26, 1988, the Court of Appeals panel (Judges Newman, Archer and Mayer -- the names are important) reversed the finding of the District Court on infringement and held that claim 1 of the patent did not require that the claimed device be limited to a surface or skin anode. However, the Federal Circuit did not address Telectronics' second argument for non-infringement, that is, the avoidance of fibrous tissue formation.

In addition, although the District Court had found that the claims were unobvious based on a narrow (the anode

being only on the skin) construction of the claims, the Federal Circuit did not remand the action back to the District Court for reconsideration of the obviousness finding based on a now broader construction of the claims.

Telectronics subsequently filed a Petition For Rehearing With Suggestion For Rehearing In Banc, but both petitions were denied by the Federal Circuit without written opinion.

REASONS FOR GRANTING THE WRIT

A. A Conflict Exists Between One Panel Of The Federal Circuit, Which Held That A Case Should Be Remanded To The Lower Court For An Application Of The Properly Construed Claims To The Prior Art, And The Federal Circuit Panel Which Reviewed This Case, Since It Did Not Remand To The District Court To Reconsider The Obviousness Question Based On The Broader Claim Interpretation

In the District Court decision, Judge Matsch specifically stated that he considered obviousness under Section 103 based only on a construction of the claims limited to a skin anode.

> The defendants contend that the '841 patent is invalid for obviousness under 35 U.S.C. Section 103, and anticipation under 35 U.S.C. Section 102. In determining these issues, the court will limit the patent to an external anode.

Accordingly, because the Federal Circuit subsequently found the claims to cover both a skin and internal anode, the

case should have been remanded to the District Court for a re-evaluation of the prior art. That is just common sense. "The more narrowly a claim is construed, the more likely it may be upheld in light of the prior art." Newell Companies v. Kenney Manufacturing Co., 9 U.S.P.Q.2d 1417, 1425 (Fed. Cir. 1988).

At trial, with respect to the prior art defenses under Section 103, Telectronics relied most heavily on two articles and related lectures, Exhibits 19 and R-2, prior art which taught the use of internal anodes. These two pieces of prior art, plus others, are now critical to Telectronics' obviousness (invalidity) position in this lawsuit, since the Federal Circuit has construed the claims to also cover internal anodes (as well as external anodes).

Nevertheless, the Court of Appeals in its decision did not remand the case

to the District Court for a re-evaluation of the obviousness question. This failure to remand is in complete contrast with a very recent decision of the Federal Circuit in Perkin-Elmer Corp. v. Westinghouse Electric Corp., 822 F.2d 1528, 1530 (Fed. Cir. 1987). In Perkin-Elmer, Westinghouse acknowledged validity only if the patent claims were interpreted narrowly. Perkin-Elmer appealed the District Court's holding of non-infringement, but Westinghouse did not appeal from the District Court's validity holding. Although the judgment appealed from was affirmed, the Court specifically commented that if it were to have concluded that the District Court's construction of the claim was legal error, the case would have to be remanded to the District Court for an application of the properly construed claims to the Westing-

house devices. The court also said that the validity of the properly construed claims would be a potential issue on remand.

This is the same situation as in this case, except that the Federal Circuit panel did reverse on infringement. In fact, at oral argument, counsel for Telectronics was asked by the Federal Circuit panel what should happen if non-infringement were to be reversed. Counsel responded that a remand to the District Court would be necessary so that validity could be re-evaluated in light of the expanded construction of the patent claims. [The same point was made in Telectronics' brief on appeal.]

Since the Federal Circuit did not remand this case to the District Court for reconsideration of validity under Section 103, the Federal Circuit panel in Perkin-Elmer and the panel in this law-

suit are in obvious conflict. What is even more striking is the fact that two of the judges in the Perkin-Elmer panel (Newman and Archer) were also on the Federal Circuit panel in this lawsuit. Nonetheless, these two judges decided to simply ignore their own precedent.

Further, as a matter of law, since Perkin-Elmer has not been overturned, the prior decision of the Federal Circuit in Perkin-Elmer was "binding precedent" on the panel in this case. Newell Companies v. Kenney Manufacturing Co., 9 U.S.P.Q.2d 1417, 1423 (Fed. Cir. 1988). [The panel in Newell also included Judges Newman and Archer, two of the judges in Perkin-Elmer and two of the judges in our case.]

Telectronics therefore urges that the Supreme Court grant certiorari in this case, in order that this conflict between two panels of the Federal Circuit

be resolved. The Supreme Court has consistently granted certiorari where there have been conflicts between two different Circuits. See Nat. Ass'n of Greeting Card Pub. v. U.S. Post. Service, 462 U.S. 810 (1983). Since the Federal Circuit is the only Circuit which decides patent matters, common sense dictates that this inconsistency between the Perkin-Elmer decision and that in this case must be resolved. Hopefully the resolution will be in Telectronics' favor. Otherwise, all parties in appeals to the Federal Circuit will be forced to discuss in depth their various prior art defenses, even if validity is not appealed, just in case there is a reversal on non-infringement.

B. The Federal Circuit Decided Not To Review The District Court's Characterization Of Telectronics' Non-Infringement Defense, Depriving Telectronics Of A Full And Fair Opportunity To Litigate

The panel of the Federal Circuit specifically construed the patent claims to include both a skin anode and an implanted anode. The panel said that Telectronics admitted that this was its only non-infringement defense.

However, Telectronics had in fact two non-infringement defenses, not just one. The first was that the claims were limited to an external anode (which defense the Federal Circuit panel considered, but rejected). The second was that, even if the claims were broad enough to encompass an internal anode, the allegedly infringing device did not avoid fibrous tissue formation (because fibrous tissue cannot be avoided if an internal anode is used).

The Federal Circuit panel based its

ruling on literal infringement in part on a single statement of the District Court:

> The defendants' denial of infringement in this case is based solely on the defendants' anode and case being used internally. Accordingly, the critical question in the case is whether the language of claim 1 (and with it, the dependent claims) is limited to a skin anode.

Once the panel had decided that Telectronics lost on the internal/external anode distinction, there was no reason to further consider the issue of infringement. In other words, the Federal Circuit believed that the District Court had said Telectronics had a <u>single</u> non-infringement defense (on which it lost), so that no further concern need be paid to any other defense of non-infringement (whether the limitation in issue, the avoidance of current-related fibrous

tissue, was really satisfied).*

Instead of considering the second defense outright, the Federal Circuit panel perhaps should have at least remanded the case back to the District Court so that Judge Matsch could rule on the second non-infringement defense, based on the Federal Circuit panel's revised interpretation of the claim (that it covers both a skin and implanted anode). This was the procedure followed in ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576 (Fed. Cir. 1988),

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* In fact, the District Court did consider Telectronics' second non-finding was based on an erroneous claim infringement defense. Both defenses are based on a single fact -- the use of an internal anode. Even if the claims embrace an internal anode, the government did not prove that Telectronics' device avoids fibrous tissue formation. Thus, sentence in the District Court opinion relied upon by the panel was, in fact, not a concession to one non-infringement defense.

where the District Court's infringement finding was based on an erroneous claim interpretation. Interestingly, Federal Circuit's Judge Archer wrote both that opinion as well as the opinion of the Federal Circuit in our case.

Telectronics never conceded that its sole non-infringement defense was that the claims were literally limited to an external anode. Even if the lower court believed that there was in fact only one defense, the Federal Circuit was not bound by what the lower court said. There is no rule, and there should not be one, that a District Court's characterization of a party's defense is sacrosanct and is immune from appellate review.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

87-1445, -1446

UNITED STATES OF AMERICA,

Plaintiff/Appellant,

and

ZIMMER, INC.,

Involuntary Plaintiff/
Counterclaim-Defendant,

v.

TELECTRONICS, INC. and
BGS MEDICAL, INC.,

Defendants/Counterclaim-
Plaintiffs/Cross-Appellants.

DECIDED: September 22, 1988

Before NEWMAN, ARCHER and MAYER, Circuit Judges.

ARCHER, Circuit Judge.

The United States of America (government) appeals the judgment of the United States District Court for the District of Colorado in United States v.

Telectronics, Inc., 658 F. Supp. 579, 3 USPQ2d 1571 (D. Colo. 1987), holding that Telectronics, Inc. and BGS Medical, Inc. (Telectronics) do not infringe U.S. Patent No. 3,842,841 ('841). Telectronics cross-appeals the determinations that the '841 patent is not invalid under 35 U.S.C. Sec. 112 (1982) and that Telectronics is not entitled to attorney fees under 35 U.S.C. Sec. 285 (1982).[1] We reverse the district court's holding that the '841 patent is not infringed by Telectronics. The determinations that the patent is not invalid under section 112 and that Telectronics is not entitled to attorney fees are affirmed.

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[1] Telectronics has not appealed the district court's holdings on other issues it raised below.

Background

The '841 patent issued to Carl T. Brighton, et al. and was assigned to the United States. The patent resulted from work under contract between the Office of Naval Research and the University of Pennsylvania, where the inventors were employed. 658 F. Supp. at 581, 3 USPQ2d at 1571. The '841 patent is directed to a bone growth stimulator device for speeding the healing of fractures and other bone defects. The accused devices of Telectronics are marketed under the name OSTEOSTIM and include Model 2000 and earlier models S-12, HS-12 and XM-12. Zimmer, Inc. (Zimmer), a licensee of the government under the '841 patent, also markets a bone growth stimulator which the district court found to be "quite similar to the preferred embodiment of the invention shown in the patent." 658 F. Supp. at 581, 3 USPQ2d at 1571.

Normally bone fractures heal naturally as a result of the body's own reparative process. Approximately five percent of the time, however, natural healing does not occur and bone grafting is conventionally employed to attempt to stimulate further reparative growth. 658 F. Supp. at 581-82, 3 USPQ2d at 1572.

Bone growth stimulators are particularly useful in the treatment of fractures normally requiring grafting. The success rate is at least as great as with grafting and the procedure results in less discomfort to the patient. 658 F. Supp. at 582, 3 USPQ2d at 1572. Bone growth stimulators expedite the healing of a fracture or bone defect by passing a low level constant direct current to the site of the fracture via a cathode placed internally at the site of the fracture. Id. The placement of the

circuit-completing anode is at issue in this case.

The claim of the '841 patent at issue reads:

> 1. A system for expediting the healing of bone fractures and bone defects in a living being comprising:
>
> constant current source means for providing a constant value of current despite changes in load;
>
> means for connecting said constant current means to the living being, such connection acting to produce current flow into said fracture or defect,
>
> said connecting means including further means for application internally of said living being at the fracture or defect site,
>
> said constant current being a selected value within a predetermined microampere range so as to promote bone formation at the fracture or bone defect site and avoid fibrous tissue formation in other areas of the living being.

In describing the operation of the

patented invention and the accused devices, the district court stated that

> [w]hen using the product of either party, the cathode (negative terminal) is placed in the defect site. The Zimmer cathode is made of stainless steel, the material described in the patent. The OSTEOSTIM cathode is made of titanium. The major difference between the products of the parties pertains to the anode (positive terminal). As disclosed in the patent drawing and accompanying description, and as marketed by Zimmer, the anode is placed on the skin of the patient. So is the power pack (current source) itself. The only internal element [in Zimmer] is the cathode -a pin which is inserted through the skin into the defect site. This technique avoids the need for surgery; after several months of treatment, the cathode pin is simply pulled out. The OSTEOSTIM device, on the other hand, is completely implanted, an embodiment which while not shown in the patent drawing is nevertheless described. The power pack and the anode of the OSTEOSTIM are placed in soft tissue near the bone. The original OSTEOSTIM S-12 had a power pack from which two wires extended, the wires terminating respectively at a titanium

> cathode for placement in the defect site, and a platinum anode for placement in the soft tissue. In all of the later models, including the OSTEOSTIM-2000, the anode wire was omitted. The anode is the case itself -- titanium with a patch of platinum.

658 F. Supp. at 582, 3 USPQ2d at 1572.

Because the Telectronics devices have an implanted anode, the district court stated that "the critical question in the case is whether the language of claim 1 (and with it, the dependent claims) is limited to a skin anode." 658 F. Supp. at 583, 3 USPQ at 1573. Telectronics contended before the district court that "an internal anode could not come within the literal language of claim 1 because fibrous tissue formation inevitably results from such an implant." Id. In finding no literal infringement, the district court held with respect to the accused device that

> fibrous tissue formation could not be avoided in the dictionary sense of "keep away from" or "stay clear of".
>
> The claim limitation directed to the avoidance of fibrous tissue means what it plainly says. Accordingly, there is no literal infringement because in the context of the patent, even minimal fibrous tissue formation is not its avoidance. Id.

The district court also held that the '841 patent was not infringed under the doctrine of equivalents on the basis that the prosecution history established that the patentees, in responding to rejections by the examiner, repeatedly represented that the invention was limited to a surface or skin anode. After examining the prosecution history in detail, the district court stated: "[i]t is clear from the file history that what convinced the Examiner to allow the claims over the prior art was the argument that a skin anode was used in

the invention.'' 658 F. Supp. at 587, 3 USPQ2d at 1576.

On appeal, the government contends that the district court in its literal infringement analysis erred as a matter of law in its claim interpretation. According to the government, the claim limitation read as a whole requires the constant current supply to be controlled in a manner to minimize the amount of fibrous tissue formed. Telectronics counters that the district court properly interpreted the claim phrase "avoid fibrous tissue formation" and the prosecution history to find that the claim is limited to the use of a skin anode.

OPINION

I. Claim Interpretation

A. Analysis of literal infringement involves two inquiries: first the

claims must be properly construed to determine their scope and then it must be determined whether the properly interpreted claims encompass the accused structure. ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1578, 6 USPQ2d 1557, 1559 (Fed. Cir. 1988). Claim construction is reviewed as a matter of law. However, interpretation of a claim may depend on evidentiary material about which there is a factual dispute, requiring resolution of factual issues as a basis for interpretation of the claim. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1054, 5 USPQ2d 1434, 1441 (Fed. Cir. 1988). In interpreting claims resort should be made to the claims at issue, the specification, and the prosecution history. Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 867, 228 USPQ 90, 93 (Fed. Cir.

1985). The question of literal infringement is a factual inquiry and is reviewed on a clearly erroneous standard. Loctite Corp., 781 F.2d at 866, 228 USPQ at 93.

B. The district court interpreted the phrase "avoid fibrous tissue formation" as precluding the use of an implanted anode, and thus limiting the claim to a surface or skin anode. To the court, the word "avoid" based on its dictionary definition meant that there could be no fibrous tissue. Because an implanted anode inevitably resulted in some fibrous tissue, the court determined that this placement of the anode was not covered by the claim language.

The government argues that the district court erred in its interpretation because the phrase at issue was not read in context. It contends that the claim language read as a whole only requires that there be avoidance or minimization

of fibrous tissue formation by controlling or selecting the current. Thus, any fibrous tissue that may result from the implantation of the anode is immaterial.

We agree that the district court erred in its interpretation of the limitation of claim 1 and in its conclusion that such language is determinative of the anode placement. In the claim, constant current is a "selected value . . . so as to promote bone formation . . . and avoid fibrous tissue formation in other areas." Nothing in this language relates to fibrous tissue that may be formed from implantation of an anode. The plain meaning of the disputed language is only that current-related fibrous tissue formation is to be avoided.

In considering other sources for interpretation of claims, we note that

the specification supports the plain meaning of the clause at issue. See Autogiro Co. of America v. United States, 384 F.2d 391, 397, 155 USPQ 697, 702-03 (Ct. Cl. 1967) ("[P]atent law allows the inventor to be his own lexicographer . . . . [t]he specification aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification.") The specification makes no mention of whether a skin anode or an implanted anode may cause or deter the formation of fibrous tissue. There is, however, a discussion of the increase or decrease in fibrous tissue that is formed with varying currents. Further, we find nothing in the prosecution history that would indicate that fibrous tissue resulting from implantation of an electrode was at issue or was intended to be covered by

the claim language.

The claim language relied on by the district court is, therefore, determinative of anode placement and does not require that claim 1 be limited to a surface or skin anode.

C. Claim 1 recites a "means for connecting said constant current means to the living being, such connection acting to produce current flow into said fracture or defect." Since this recitation is in the "means plus function" format permitted by 35 U.S.C. Sec. 112, Para. 6, it must be interpreted to cover the structure disclosed in the specification and the equivalents thereof. See D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1575, 225 USPQ 236, 239 (Fed. Cir. 1985).

"In construing a 'means plus function' claim, as also other types of claims, a number of factors may be consi-

dered, including the language of the claim, the patent specification, the prosecution history of the patent, other claims in the patent, and expert testimony [citations omitted]. Once such factors are weighed, the scope of the 'means' claim may be determined." Palumbo v. Don-Joy Co., 762 F.2d 969, 975, 226 USPQ 5, 8 (Fed. Cir. 1985); see also Moeller v. Ionetics, Inc., 794 F.2d 653, 656, 229 USPQ 992, 994 (Fed. Cir. 1986) (resort to extrinsic evidence, such as the prosecution history, is necessary to interpret disputed claims); SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n, 718 F.2d 365, 376, 218 USPQ 678, 688 (Fed. Cir. 1983) (the prosecution history is always relevant to proper claim interpretation). "[T]he prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been dis-

claimed or disavowed during prosecution in order to obtain claim allowance." Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452, 227 USPQ 293, 296 (Fed. Cir. 1985); see also McGill Inc. v. John Zink Co., 736 F.2d 666, 673, 221 USPQ 944, 949 (Fed. Cir.), cert. denied, 469 U.S. 1037 (1984).

The district court found that both implanted and surface anodes are disclosed in the specification of the '841 patent. The specification provides: "[a]lthough the cathode must be placed in the fracture . . . the anode, though described as preferably being placed on the remote side of the site from the cathode, may be placed anywhere so long as it completes a circuit with the cathode." Elsewhere the specification provides that "[i]f the anode is to be implanted, it . . . is bared of its

cover." Thus, unless other relevant claim interpretation factors clearly require a different construction, the plain language of claim 1 and the specification cover an implanted anode as well as a skin or surface anode.

In its claim construction and literal infringement analysis, the district court did not consider the prosecution history but concluded for the reasons indicated in I.A., supra, that a surface anode was required. The prosecution history, however, was extensively discussed in the court's consideration of the doctrine of equivalents.

Prior to allowance, the applicants communicated with the examiner six times. These communications are referred to as "A" through "F" in the district court's opinion and herein. The district court concluded that because of the prosecution history appellant is "prevented from

construing its claims to include an internal anode." 658 F. Supp. at 587, 3 USPQ2d at 1577. We disagree.

The district court first relied on Amendments B and C. In the former, applicants inserted the limitation "only one of said connecting means applied to the skin surface of the living being" for the purpose of attempting to overcome a prior art rejection. This amendment was accompanied by remarks to the same effect. In Amendment C, this limitation was argued to be a distinguishing feature of the invention. Applicants' attempts to distinguish over the prior art in this fashion were unsuccessful, and the claims were later amended to remove this recitation. The arguments emphasizing the use of a skin electrode, which were made at the time the application claims explicitly contained such a limitation, cannot

furnish a basis for restricting issued claim 1, which lacks any such limitation. See Smith v. Snow, 294 U.S. 1, 16 (1935) ("It is of no moment that in the course of the proceedings in the Patent Office the rejection of narrow claims was followed by the allowance of the broader Claim 1."); Kistler Instrumente AG v. United States, 628 F.2d 1303, 1308, 211 USPQ 920 (Ct. Cl. 1980) (aff'g and adopting 203 USPQ 511, 516) (courts are not permitted to read "back into the claims limitations which were originally there and were removed during prosecution of the application through the Patent Office.")

In Amendment D a claim which ultimately issued as independent claim 1 was submitted for the first time. In holding claim 1 should be limited to a skin anode, the district court relied on Amendments E and F which contained argu-

ments relative to a skin anode and which were held by the district court to be in support of the claims that finally .pa issued.[2] From Amendment F the district court quoted the following language:

> Applicants take strong exception to [the examiner's] analysis of the [Friedenberg-Kohanim article]. Nowhere in this article is there either stated or suggested that one of the electrodes need simply be applied to the surface and the other introduced into the fracture site.

These remarks were submitted to correct the examiner's characterization of a prior art reference (an article written

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[2] There was some uncertainty as to which set of claims certain of these remarks applied, but the district court found that Amendments E and F related to the claims presented in Amendment D. Because we conclude that the district court erroneously limited the claims even if the remarks in controversy did apply to the claims which issued, we need not determine whether the district court correctly resolved this dispute.

by one of the co-inventors of the

patented invention). The examiner's characterization of the reference was made in rejecting claims, at least some of which included an explicit recitation of a surface anode. Thus, these remarks are of little significance.

The district court also noted the following argument in Amendment F:

> Applicants throughout the prosecution of this case have repeatedly attempted to convey to the Examiner the important differences between their technique where only one of the electrodes need pierce the skin and enter the fracture site and the other prior art arrangements where two electrodes have to pierce the skin and then fit into prescribed locations formed in the bone structure under study. (Emphasis added.)

The quoted language does not mean that one electrode must remain on the surface of the skin. Rather, as applicants argue, it means that both of their electrodes do not have to be placed in the bone structure itself. The district

court erred in construing the phrase "only one of the electrodes need pierce the skin" to mean that the other electrode must remain on the surface. This phrase, when read in conjunction with the words that follow--"and enter the fracture site"--only serves to distinguish prior art where both electrodes were placed in the bone structure.[3] The entire emphasis of the prior art article was that the electrodes were placed in the bone for the purpose of attempting to lengthen the bone. The article was not concerned with the healing of fractures or bone defects.

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[3] The district court recognized that ''[t]here are three possible positions for placement of the anode: on the skin, in soft tissue, and in the bone. Placement within the bone must be done carefully to avoid the effect of insulation from the cortical bone." 658 F. Supp. at 583, 3 USPQ2d at 1573. In the healing of fractures, it is not

necessary (or desirable) to place both electrodes in the bone.

D. "There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant." Tandon Corp. v. United States Int'l Trade Comm'n, 831 F.2d 1017, 1023, 4 USPQ2d 1283, 1288 (Fed. Cir. 1987). "Where some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad whether to avoid invalidity or to escape infringement. Uniroyal, Inc., 837 F.2d at 1054-55, 5 USPQ2d at 1441 (quoting D.M.I., Inc. v. Deere & Co., 755 F.2d at 1574, 225 USPQ

at 239).

In this case the district court erroneously construed claim 1 so that its limitations are the same as dependent claim 2. Claim 2 reads in its entirety: "The system as defined in claim 1 wherein said connecting means includes means for external application to the skin surface, the internal means being a cathodic electrode, the external means being an anodic electrode." The doctrine of claim differentiation, therefore, counsels against limiting claim 1 to the use of a skin anode. See D.M.I., Inc., 755 F.2d at 1574, 225 USPQ at 239.

E. On the basis of the above analysis, we conclude that the district court erred as a matter of law in its interpretation of claim 1 of the '841 patent. Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983).

The ordinary and accustomed meaning of claim 1 is that the current should be applied so as to avoid the formation of fibrous tissue. In support of this means plus function claim, the specification of the '841 patent disclosed both an implanted and a surface anode structure. The other claims, the specification and the prosecution history do not require a narrower construction. Thus, the district court erred in limiting claim 1 to the use of a skin anode.

II. Literal Infringement

The question of literal infringement is a factual inquiry. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d at 1054, 5 USPQ2d at 1441. Literal infringement requires that every limitation of the patent claim must be found in the accused device. Mannesmann Demag Corp. v. Engineered Metal Prods. Co., 793 F.2d

1279, 1282, 230 USPQ 45, 46 (Fed. Cir. 1986). In this case, the findings of the district court establish literal infringement and, thus, there is no need to remand for a determination of the factual question of infringement under properly interpreted claims.

The district court stated in its opinion that:

> The defendant's denial of infringement in this case is based solely on the defendants' anode and case being used internally. Accordingly the critical question in the case is whether the language of claim 1 (and with it the dependent claims) is limited to a skin anode.

As we have held in I., supra, the properly construed claims encompass both a skin anode and an implanted anode. The district court erroneously limited the claims of the '841 patent to a surface anode. Accordingly, on the position of Telectronics as stated by the district

court, literal infringement is established.

The government also challenges the district court's finding of no infringement under the doctrine of equivalents. Because the accused devices literally infringe, a doctrine of equivalents inquiry is unnecessary. See ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d at 1581, 6 USPQ2d at 1562 ("When literal infringement is not found, the equitable doctrine of equivalents comes into play.").

III. Invalidity

The district court held: "[i]f claim 1 were to be given the broad meaning which plaintiff asserts, then the patent would be invalid for a failure to comply with the specification requirements of 35 U.S.C. Sec. 112." 658 F. Supp. at 589, 3 USPQ2d at 1577-78.

According to the district court a dose response study must be performed for materials other than stainless steel to determine the optimal electrical current to be supplied and this would involve "an undue amount of experimentation." Id.

In its cross-appeal Telectronics argues that the patent is invalid for non-enablement regardless of how the claims are interpreted because the disclosure does not bear a reasonable relationship to the scope of the claims.

Enablement is a legal determination which is reviewed as a matter of law. Raytheon Co. v. Roper Co., 724 F.2d 951, 951-60, 220 USPQ 592, 599 (Fed. Cir. 1983). To be enabling under section 112, the patent must contain a description sufficient to enable one skilled in the art to make and use the claimed invention. Id. A patent may be enabling even

though some experimentation is necessary; the amount of experimentation, however, must not be unduly extensive. Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). A patent is presumed valid, and the burden of proving invalidity, whether under section 112 or otherwise, rests with the challenger. Invalidity must be proven by facts supported by clear and convincing evidence. Ralston Purina Co. v. Far-Mar-Co., Inc., 772 F.2d 1570, 1573-74, 227 USPQ 177, 178 (Fed. Cir. 1985) ("A party asserting invalidity based on 35 U.S.C. Sec. 112 bears no less a burden . . . than any other patent challenger.") Thus, although not mentioned by the district court, it is Telectronics' burden to show by facts supported by clear and convincing evidence that the patent was not enabling.

We note first that Telectronics

admits that "[t]he patent does disclose how to successfully practice the invention -- if stainless steel electrodes and a current in the range of 5-20 microamperes is [sic] used." (Emphasis in original.) Lack of enablement is asserted on the basis that "the claims are not limited to the specific metal/current combination."

The district court thought that to determine the optimal electrical current for materials other than stainless steel a dose response study would be required and that this would involve an "undue amount of experimentation." The district court said "the patent does not tell a person reasonably skilled in the art how to make and use this invention because it fails to teach how to select a level of current to promote bone formation and avoid fibrous tissue . . . formation from

such current" for electrodes made of materials other than stainless steel. 658 F. Supp. at 589, 3 USPQ2d at 1578. It noted that "the patent does not contain an adequate description of the methodology for a dose response study for any cathode material other than stainless steel" and that "only those who were expert in the field and actually working with bone, doing electrical stimulation experiments . . . would know how to conduct" such a study. Moreover, the district court thought that the time and expense of such a study also indicated undue experimentation would be required.

We are convinced that these findings and conclusions are insufficient to constitute clear and convincing proof of invalidity. First, it is undisputed that the patent disclosures are enabling with respect to stainless steel electrodes, with the range of current for such elec-

trode set out in the specification. The specification shows this range of current was obtained by a dose response test. Next, according to the district court "those who were expert in the field and actually working with bone, doing electrical stimulation experiments . . . would know how to conduct a dose response study to determine the appropriate current to be used with other materials as electrodes." Id. The appropriate levels of current for other electrodes to promote bone growth and avoid fibrous tissue could, therefore, be determined. Finally, the emphasis by the district court on the time and cost of such studies is misplaced. While these factors may be taken into account, in the circumstances of this case we are unpersuaded that standing alone they show the experimentation to be excessive. The

test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 107 S. Ct. 1606 (1987).

Since one embodiment is admittedly disclosed in the specification, along with the general manner in which its current range was ascertained, we are convinced that other permutations of the invention could be practiced by those skilled in the art without undue experimentation. See SRI Int'l v. Matsushita Elec. Corp. of America, 775 F.2d 1107, 1121, 227 USPQ 577, 586 (Fed. Cir. 1985) (the law does not require an applicant to describe in his specification every conceivable embodiment of the

invention); Hybritech Inc., 802 F.2d at 1384, 231 USPQ at 94 (the enablement requirement may be satisfied even though some experimentation is required). While perhaps fortuitous, as the district court found, the OSTEOSTIM device of Telectronics used a current level of 20 microamperes, within the "substantially 5 microamperes to substantially 20 microamperes" range set forth in claim 5 and disclosed in the specification.

The district court also held that if claim 1 is read to mean that the current must be applied so as to minimize fibrous tissue formation then it would be invalid under 35 U.S.C. Sec. 112 (1982) because it would be "impossible to determine when sufficient minimization takes place to determine what current range is involved." 658 F. Supp. at 589, 3 USPQ at 1578. The district court erred as a

matter of law in this holding. Shatterproof Glass Corp. v. Libby-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir.), cert. dismissed, 106 S. Ct. 340 (1985). Section 112, Para. 2, requires only reasonable precision in delineating the bounds of the claimed invention. Id. Adjusting current so as to minimize fibrous tissue formation in other parts of the living being reasonably apprises those skilled in the art of the bounds of the claimed invention and is as precise as the subject matter permits. See id. Thus, we hold as a matter of law that the '841 patent is enabling and that the claims satisfy 35 U.S.C. Sec. 112, Para. 2.

In its cross appeal, Telectronics argues that the specification is enabling only for the use of stainless steel while the claims are not limited in the types of material from which the electrodes can

be made. It contends that the scope of the protection must bear a reasonable relationship to the scope of enablement, citing In re Fisher, 427 F.2d 833, 838-39, 166 USPQ 18, 23-24 (CCPA 1970) ("In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."), and In re Bowen, 492 F.2d 859, 861-64, 181 USPQ 48, 50-52 (CCPA 1974) (section 112 requires that the scope of claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art). Fisher and Bowen both involved chemical reactions, recognized by our predecessor court as having a high degree of unpredictability and therefore requiring an

increased enablement disclosure. Yet, in Bowen the board's non-enablement rejection was reversed where the "claims literally comprehend numerous polymers in addition to the one specifically described in appellant's specification" because no persuasive reason was given by the Patent Office why the specification does not realistically enable one skilled in the art to practice the invention as broadly as it is claimed. In re Bowen, 492 F.2d at 863, 181 USPQ at 51-52. The same can be said here. The only impediments are the time and cost of a dose response study, which the district court found could be performed by "those who were expert in the field and actually working with bone, doing electrical stimulation experiments . . .," i.e., those skilled in the art. Moreover, as we have noted, Telectronics' device using different electrode materials actually

operated within the current parameters disclosed in the specification.

We conclude that the district court erred in its nonenablement conclusion and that facts supported by clear and convincing evidence of invalidity were not adduced.

In view of our decision, we need not consider the district court's denial of attorney fees to Telectronics.

Costs

The parties shall bear their respective costs.

AFFIRMED-IN-PART AND REVERSED-IN-PART

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

87-1445, -1446

UNITED STATES OF AMERICA,

Plaintiff/Appellant,

and

ZIMMER, INC.,

Involuntary Plaintiff/
Counterclaim-Defendant,

v.

TELECTRONICS, INC. and
BGS MEDICAL, INC.,

Defendants/
Countercliam-Plaintiffs/
Cross-Appellants.

Before NEWMAN, ARCHER and MAYER,
Circuit Judges.

O R D E R

A petition for rehearing having been filed in this case,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for

rehearing be, and same hereby is, denied.

The suggestion for rehearing in banc is under consideration.

FOR THE COURT

Francis X. Gindhart,
Clerk

Dated: November 23, 1988

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

87-1445, -1446

UNITED STATES OF AMERICA,

Plaintiff/Appellant,

and

ZIMMER, INC.,

Involuntary Plaintiff/
Counterclaim-Defendant,

v.

TELECTRONICS, INC. and
BGS MEDICAL, INC.,

Defendants/
Counterclaim-Plaintiffs/
Cross-Appellants.

JUDGMENT

ON APPEAL from the United States District Court for the District of Colorado

in CASE NO(S). 80-M-981

This CAUSE having been heard and considered, it is ORDERED and ADJUDGED:

AFFIRMED-IN-PART AND REVERSED-IN-PART.

DATED: September 22, 1988

ENTERED BY ORDER OF THE COURT: Francis X. Gindhart, Clerk

ISSUED AS A MANDATE: November 30, 1988

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 80-M-981

UNITED STATES OF AMERICA,

Plaintiff,

and

ZIMMER, INC.,

Involuntary Plaintiff and
Counterclaim Defendant,

v.

TELECTRONICS, INC. and
BGS MEDICAL, INC.,

Defendants and
Counterclaim-Plaintiffs.

FINDINGS OF FACT,
CONCLUSIONS OF LAW, AND ORDER

This is an action for patent infringement under 35 U.S.C. Sec. 271. The court has jurisdiction under 28 U.S.C. Sec. 1338. Plaintiff United States owns Patent No. 3,842,841, entitled "Constant Current Power Pack For Bone Healing And Method Of Use," issued

on October 22, 1974 on an application filed on October 29, 1971 in the names of Drs. Carl T. Brighton, Zachary B. Friedenberg, and William Redka, as inventors. For convenience, this patent will be referred to as the '841 patent, or Brighton patent. The plaintiff alleges infringement of claims 1, 3, 4 and 5. The patent resulted from work done in performing a contract between the Office of Naval Research and the University of Pennsylvania. The named inventors were all employed by the University of Pennsylvania.

Involuntary plaintiff Zimmer, Inc. was granted a limited exclusive license in the Brighton patent by the Navy on or about October 31, 1977, for a term of ten years.

The patented invention is a device for expediting the healing of fractures and other bone defects. The devices

involved are generally known as bone growth stimulators, and Zimmer's is sold under the trademark Zimmer DCBGS. The Zimmer device is quite similar to the preferred embodiment of the invention shown in the patent.

Defendant Telectronics, Inc. is an Australian-owned medical technology company whose main place of business is in Englewood, Colorado. Defendant BGS Medical, Inc. is a related corporation, also located in Englewood, and is the entity under whose name the business is now conducted. The trademark used by defendants for their product is OSTEOSTIM. While the Model 2000 is now being sold, earlier models were the S-12, HS-12 and XM-12. The OSTEOSTIM-2000 is the same in all relevant respects to all single-anode bone growth stimulator devices designed to expedite the healing of long bone

fractures previously manufactured or sold by defendants Telectronics and BGS Medical Corporation, or their predecessors, or Telectronics Proprietary, Limited. The accused device in this case will be referred to as the OSTEOSTlM.

The Brighton patent is directed toward a device for expediting the healing of a fracture or bone defect through the use of a low level constant direct current applied to the site of the fracture via a cathode placed internally at the site of the fracture. Such devices are sometimes referred to as direct current ("DC") bone growth stimulators. The only direct current bone growth stimulators approved for use in the United States are the Zimmer DCBGS (or Quadpak) and the OSTEOSTIM made by defendants.

Normally fractures of bones heal naturally as a result of the body's own reparative process in several stages.

First, inflammation occurs at the point of injury followed by the formation of soft callus, which is cartilage. This gives way to hard callus formation, in which the soft cartilaginous tissue is replaced with fiber bone. Finally, remodelling occurs in which the fiber bone is replaced with lamellar bone. In bridging the fracture, the first bone formed is subperiosteal, i.e., below the periosteum which is the outer surface of the cortex of the bone. Endosteal bone also forms to bridge the fracture on the inside of the bone. Then the interfragmentary gap is filled with new bone, uniting the cortices.

DC bone growth stimulators are particularly useful in the treatment of nonunions. A nonunion is a fracture which has not healed naturally within an extended period of time, and in which all

natural reparative processes have ceased. Nonuninons occur in about 5% of all long bone fractures. Prior to the advent of direct current bone growth stimulators, the conventional treatment for a nonunion was bone grafting, which involved removing a portion of the hip bone of the patient and grafting this portion to the nonunion, in the hope that it will stimulate further bone growth and result in a healed fracture. Bone grafting involves major surgery, is painful to the patient and requires about 4-10 days of hospitalization. If the first bone graft is not successful, another must be tried. If this is not successful, the limb may be amputated.

DC bone growth stimulators have been successful in treating nonunions, even in instances where bone grafting has previously failed. The Zimmer Quadpak and the Telectronics OSTEOSTIM enjoy a suc-

cess rate of about 70-85% in healing nonunions. This is at least as good as the rate of success using bone grafting and avoids the necessity for removal of a portion of the patient's hip for a graft, along with the attendant pain. Furthermore, use of a bone growth stimulator saves hospitalization time, and its attendant costs, over that required for bone grafting.

The four claims of the patent alleged to be infringed are as follows:

> 1. A system for expediting the healing of bone fractures and bone defects in a living being comprising:
>
> constant current cource means for providing a constant value of current despite changes in load;
>
> means for connecting said constant current means to the living being, such connection acting to produce current flow into said fracture or defect,
>
> said connecting means including further means for application internally of said living being at the fracture or defect site,

said constant current being a selected value within a predetermined microampere range so as to promote bone formation at the fracture or bone defect site and avoid fibrous tissue formation in other areas of the living being.

3. The system as defined in claim 1 wherein said constant current means comprises miniature solid state means suitable for mounting on the living being in close proximity to said fracture or defect.

4. The system as defined in claim 1 wherein said cathodic electrode is positionable within said fracture or defect.

5. The system as defined in claim 1 wherein said current is in the range of from substantially 5 microamperes to substantially 20 microamperes.

Exhibit 1.

The magnitude of the constant current in the embodiment of the invention illustrated in the patent is 10 microamperes, although a range of 5-20 microamperes is said to be useful. Defendants use a constant current of 20 microamperes. When using the product of

either party, the cathode (negative terminal) is placed in the defect site. The Zimmer cathode is made of stainless steel, the material described in the patent. The OSTEOSTIM cathode is made of titanium. The major difference between the products of the parties pertains to the anode (positive terminal). As disclosed in the patent drawing and accompanying description, and as marketed by Zimmer, the anode is placed on the skin of the patient. So is the power pack (current source) itself. The only internal element is the cathode -- a pin which is inserted through the skin into the defect site. This technique avoids the need for surgery; after several months of treatment, the cathode pin is simply pulled out. The OSTEOSTIM device, on the other hand, is completely implanted, an embodiment which while not shown in the

patent drawing is nevertheless described. The power pack and the anode of the OSTEOSTIM are placed in soft tissue near the bone. The original OSTEOSTIM S-12 had a power pack from which two wires extended, the wires terminating respectively at a titanium cathode for placement in the defect site, and a platinum anode for placement in the soft tissue. In all of the later models, including the OSTEOSTIM-2000, the anode wire was omitted. The anode is the case itself titanium with a patch of platinum.

Literal Infringement

The defendants' denial of infringement in this case is based solely on the defendants' anode and case being used internally. Accordingly, the critical question in the case is whether the language of claim 1 (and with it, the dependent claims) is limited to a skin anode.

The defendants' contention is that an internal anode could not come within the literal language of claim 1 because fibrous tissue formation inevitably results from such an implant. Therefore, fibrous tissue formation could not be avoided in the dictionary sense of "keep away from" or "stay clear of". Webster's Third New International Dictionary, 151 (1971).

The patent is for a medical device -- an apparatus which will promote healing. To accomplish that purpose, it must, of course, avoid injury or adverse medical results. It must not do damage. Fibrous tissue forms as a response to a foreign body. That is called encapsulation. Fibrous tissue also results from any trauma. Electrical current produces fibrous tissue. Fibrinoid necrosis is the term used to describe dead fibrous

tissue. Fibrinoid necrosis is damage which must be avoided.

The defendants made a conscious decision not to avoid the formation of fibrous tissue, electing to tolerate the amount formed from implanting the case/anode because its effect is not so deleterious as to outweigh the benefit of greater freedom of movement for the patient. Additionally, an implanted case/anode does not have a wire penetrating the skin and thus the risk of infection is reduced. Drs. Brighton and Friedenberg, on the other hand, chose to avoid the two surgical procedures necessary for implant and explant.

The claim limitation directed to the avoidance of fibrous tissue means what it plainly says. Accordingly, there is no literal infringement because in the context of the patent, even minimal fibrous tissue formation is not its avoidance.

Infringement Under the Doctrine of Equivalents

Although literal infringement has not been proven, the plaintiff claims infringement under the doctrine of equivalents contending that the OSTEOSTIM performs substantially the same function in substantially the same way to obtain the same result. The plaintiff recognizes the ambiguities in the language of claim 1 and asserts that the last phrase should be read to mean: "said constant current being a selected value within a predetermined microampere range so as to promote bone formation at the fracture or defect site, and minimize fibrous tissue formation and subsequent necrosis of that tissue that is related to current." Plaintiff's Requested Findings of Fact and Conclusions of Law, p. 30 n. 5.

The anode's function is to return current so that the circuit is completed

and, in this regard, the anode may be placed anywhere as long as this function is served. There are three possible positions for placement of the anode: on the skin, in soft tissue, and in the bone. Placement within the bone must be done carefully to avoid the effect of insulation from the cortical bone.

The inventors of the Brighton patent conducted animal experiments which were described in the patent and in which the cathode was inserted into the fracture or bone defect site, and the anode fastened in soft tissue. Using stainless steel, the current levels used produced different results. At 1 to 5 microamperes there was little reaction at either the anode or the cathode site. At 10 to 20 microamperes there was a dark discoloration around the anode, but no discoloration at the cathode. At 50 to 100 micro-

amperes, marked discoloration occurred at both electrode sites.

Analysis of these results demonstrated that fibrous tissue formation at the anode reached a maximum at ten microamperes and at current levels higher than ten tissue destruction occurred with a maximum being attained at twenty microamperes and persisting through one hundred microamperes. That tissue destruction was that of fibrinoid necrosis.

In the patent description, the inventors described the work with human subjects as being limited to external anodes and power pack.

The plaintiff's position is that the meaning of claim 1 is that because all fibrous tissue formation cannot be prevented where the anode is implanted, care must be taken to use a sufficiently-high level of current within the predetermined healing range to promote bone formation

at the cathode in the defect site, and yet not be so high as to cause substantial fibrous tissue formation at the anode, and thereby avoid the development of fibrinoid necrosis.

Stated simply, the plaintiff claims that the adverse effect to be avoided is fibrinoid necrosis; that it is avoided in the Brighton patent by a constant controlled current within a predetermined range which is 5 microamperes for stainless steel electrodes, and that the defendants avoid fibrinoid necrosis by using a platinum electrode with a constant current of 20 microamperes. Thus, since the defendants' devices are admittedly substantially similar in all other pertinent aspects, there is infringement under the doctrine of equivalents.

The resolution of this issue requires careful consideration of the pro-

secution history of the application for the Brighton patent because the defendants contend that the inventors narrowed the scope of the claims by excluding the internal anode to avoid prior art and thereby obtain their patent.

The Brighton patent issued from application Serial No. 193,728 filed on October 29, 1971. It contained the following claims:

> Application Claim 1
>
> A means for supplying a constant current across bone fractures and defects in a living body to promote more rapid healing thereof comprising:
>
> a power source adapted to provide a substantially constant current supply to the region of said fracture or defect notwithstanding changes in impedance there across during healing thereof.
>
> Application Claim 2
>
> The means as defined in Claim 1 wherein said power source includes an electrode implanted at the site of the fracture or defect and an electrode applied to the surface of said body.

Application Claim 3

> The means as defined in Claim 2 wherein said current is in the range of substantially 5 microamperes to substantially 20 microamperes.

Exhibit 2, p. 10.

In an Office Action mailed January 8, 1973, the Examiner rejected the claims both for failure to distinctly claim the invention as required by 35 U.S.C. Sec. 112 and for anticipation and obviousness under 35 U.S.C. Secs. 102 and 103. Claims 1-3 were rejected as unpatentable over Gershen patent 3,317,817 and Warner patent 3,179,892. The Examiner also cited an article written by Dr. Andrew Bassett, Robert Pawluck and Robert Becker entitled "Effects of Electrical Currents on Bone In Vivo," published in the 1964 edition of Nature [hereinafter referred to as the 1964 Nature article], in rejecting other claims.

Amendment B was filed in response to

this Office Action on March 13, 1973. The claims were canceled and new claims 14-26 presented. The following application claims 14-18 are pertinent to the claims in dispute:

Application Claim 14

A system for expediting the healing in vivo of bone fractures and bone defects comprising:

a source of constant dc current; and

means connecting said source of constant current to the living being so as to produce current flow into said fracture or defect,

only one of said connecting means applied to the skin surface of the living being,

said constant current into said fracture or defect being maintained within a selected microampere level so as to promote bone formation at the fracture or bone defect site and avoid fibrous tissue formation in other areas of the living being.

Application Claim 15

The system as defined in claim 14 wherein said connecting means applied to the skin surface is an anode,

said connecting means

including a cathode implanted at the site of said fracture or defect.

Application Claim 16

The system as defined in claim 15 wherein said source of constant current is a miniature solid state device mounted on the living being in close proximity to said fracture or defect.

Application Claim 17

The system as defined in claim 16 wherein said cathode is positioned in said fracture or defect.

Application Claim 18

The system as defined in claim 17 wherein said current is in the range of from substantially 5 microamperes to substantially 20 microamperes.

Exhibit 2, pp. 28-30.

The Navy argued that the 1964 Nature article did not concern bone healing but only taught that "some new bone formation may be produced within the medullary canal by current flow between a pair of electrodes inserted thereinto." Exhibit 2, p. 36. It distinguished the Nature article from the amended claims on three

grounds; namely,

> No reference teaches or suggests the present inventive concept, namely that current flow across a fracture or defect may be induced to effectively enhance healing. The references also do not teach or suggest inserting one electrode in the being at the site of the fracture and applying the other electrode to the skin of the being in the vicinity of the fracture. A further deficiency in the references is an identification of the current levels within which healing is enhanced and outside of which undesirable effects are encountered.

Exhibit 2, p. 36.

The Examiner replied to Amendment B by again rejecting the claims as unpatentable in an Office Action mailed June 8, 1973. The Examiner stated that the 1964 Nature article teaches a bone growth stimulator "employing [a] D.C. (battery) source with a current within the claimed ranges and substantially constant after an initial transient re-

sponse (Fig. 2), located near the defect (i.e. drill hole) of the bone, at least one electrode implanted in the defect and another circuit-completing electrode connected between the body and the source." Exhibit 2, p. 41.

The Examiner said that it would be obvious to substitute a solid state constant current source for the Bassett device's "large value resistor" and that it would further be obvious to use a surface electrode in light of Mirowski patent 3,614,955. Exhibit 2, pp. 41-42. The Mirowski patent is directed to a "Standby Defibrillator and Method of Operation." A standby defibrillator is a device for monitoring the rhythm of the heart and delivering a short high voltage shock to counteract fibrillation. It uses one electrode positioned in the right ventricle of the heart and a second electrode which is either placed on the

skin, sutured under the skin or applied to the outer surface of the heart. When heart fibrillation is sensed, it delivers a shock of approximately 2500 volts to the heart. The Examiner noted that this rejection was a final action.

The applicants submitted amendment C on August 9, 1973. New claims 27-39 were presented. Claim 27, corresponding to claim 1 of the patent, explicitly defined a skin electrode, and the last limitation once again dealt with the avoidance of fibrous tissue formation. The remarks which accompanied the amendment included several arguments which distinguished the claimed invention from the prior art because of the use of a skin anode. Notably, the Navy lawyers said:

> It is submitted that the foregoing references are completely deficient insofar as anticipating the present invention. In the invention, current is induced across a frac-

> ture by an electrode inserted at the site thereof and a second electrode applied to the skin of the living being. There is no teaching in, or continuity among, Bassett et al, Hurd, III and Mirowski et al by which a person, having only these three references, could arrive at applicant's invention.

Exhibit 2, p. 56.

In an Advisory Action of September 6, 1973, the Examiner informed the applicants' attorney that the new claims had not been entered, and that old claims 14-26 still stood rejected. On September 21, 1973, Amendment D was filed. Application claims 14-26 were submitted. Application claims 14-18 are identical to claims 1-5 of the issued patent. There is no dispute that the claims of Amendment D were entered. The amendment, as it appears in the prosecution history produced by the Patent and Trademark Office contains a handwritten note "OK to enter WEK" and handwritten renumbering of

the claims from 14-26 to 27-39, with the initials "WEK" appearing next to some of the renumbered claims. Apparently, the Examiner renumbered the application claims. The remarks section of the amendment specifically states that the claims were being amended as agreed at an interview held with the Examiner on September 16, 1973.

In an Office Action mailed November 6, 1973, the Examiner withdrew his final rejection and rejected the claims under 35 U.S.C. Sec. 102 as unpatentable over the Friedenberg 1970 Surgery, Gynecology and Obstetrics article, and under 35 U.S.C. Sec. 103 and Sec. 102 as unpatentable over the Friedenberg 1968 article dealing with stimulation of the growth plate and an article by Assimacopoulous dealing with the use of current to heal wounds. There is confusion as to which

set of claims was being examined, the claims numbered 27-39 submitted in Amendment C or the amended claims numbered 14-26 submitted in Amendment D, which the Examiner renumbered.

The issue is important because responsive Amendment E, Exhibit 2, pp. 73-79, filed on December 7, 1973, while not containing any changes to the claims, did contain an argument -- directed to claims 27-39 -- which focused on a skin anode. Defendants assert that the argument was directed to the claims of Amendment D; since claim 27 of Amendment D was identical to patent claim 1, patent claim 1 is to be interpreted as being limited to the use of a skin anode. Plaintiff asserts that the argument in Amendment E was directed to claim 27 of Amendment C, this claim explicitly defining a skin anode; it was later that the claims of the patent were submitted again, and the

previous argument about a skin anode applied only to claim 27 of Amendment C which explicitly defined a skin anode.

On conflicting evidence, this court finds that the Office Action of November 6, 1973 rejected the claims of Amendment D, not the claims of Amendment C. The claims of Amendment C were not entered and the applicants' attorney was told this in an Advisory Action. It would be highly unusual for an Examiner to decide to enter claims in such a case and not tell the applicants' attorney. There is no question that the claims of Amendment D were entered. Amendment C was filed prior to the interview which was held on September 16, 1973, Amendment D was not only filed after the interview, but specifically states that the claims were based on what transpired at the interview, and the remarks of Amendment E also

refer to the interview. The claims in Amendment C were not rejected in view of the prior art (they were simply not entered), while the claims of Amendment D were rejected in view of the three new references; the argument of Amendment E distinguished claims 27-39 from these references so it must be the claims of Amendment D which the attorney had in mind because they were the only claims which had been rejected in view of these references. Although no argument was presented in Amendment D, the remark was made that the claims were being amended "in accordance with the changes which the Examiner agreed would remove his objections." Exhibit 2, p. 66.

It is unlikely that an attorney, who thought that he had reached an agreement with the Examiner on a second group of claims but then discovered that the Examiner was still not convinced, would

have argued in Amendment E about another completely different first group of claims without even telling the Examiner. At any rate the question is not what the applicants thought they were construing. What they were thinking is irrelevant. It is what was said that counts; an estoppel would arise based upon the effect of the argument on the Examiner. It is clear from the Office Action which followed the filing of Amendment E that the Examiner had previously had in mind the claims of Amendment D. The Examiner continued to reject the claims as unpatentable over the 1968 Friedenberg article in light of the Assimacopoulous article. He reasoned that the 1968 Friedenberg article taught a means of expediting growth at the fracture site including using a substantially constant current, an external anode and an

internal cathode at the point of desired growth. He said that while the Friedenberg 1968 article did not involve the use of constant current, it would be obvious to modify the device disclosed in that article to include a constant current source in light of the Assimacopoulous article. The Examiner made this rejection final.

The Navy attorney, in Amendment F, filed another set of claims, this time numbered 40-52, but otherwise identical with the claims of Amendment D; it was these claims which were ultimately allowed.

The remarks which accompanied the claims in Amendment F included the following argument:

> . . . Applicants take strong exception to this analysis of the [Friedenberg-Kohanim article, Exhibit 4] reference. Nowhere in this article is there either stated or sug-

> gested that one of the electrodes need simply be applied to the surface and the other introduced into the fracture site. . . .

Exhibit 2, p. 92.

The argument for allowability of the submitted claims continued as follows:

> Applicants throughout the prosecution of this case have repeatedly attempted to convey to the Examiner the important differences between their technique where only one of the electrodes need pierce the skin and enter the fracture site and the other prior art arrangements where two electrodes have to pierce the skin and then fit into prescribed locations formed in the bone structure under study.

Exhibit 2, p. 93.

Together with Amendment F there was submitted an affidavit by several of the co-authors of the Friedenberg 1970 Surgery, Gynecology & Obstetrics article which the Examiner had cited. That affidavit states that "the concept of disposing a cathode electrode in the fracture

site and positioning the anode electrode on the skin surface of the subject originated with our co-authors, Drs. Friedenberg and Brighton . . . " Exhibit 2, p. 97. It is clear from the file history that what convinced the Examiner to allow the claims over the prior art was the argument that a skin anode was used in the invention. The doctrine of prosecution history estoppel "bars a patentee from construing its claims in a way that would resurrect subject matter previously surrendered during the prosecution of the patent application, and thus prevents a patentee from enforcing its claims against otherwise legally equivalent structures if those structures were excluded by claim limitations in order to avoid prior art." Mannesman Demag Corp., v. Engineered Metal Products Co., 793 F.2d 1279, 1284 (Fed. Cir. 1986). Accordingly, the plaintiff is

prevented from construing its claims to include an internal anode.

Claim Differentiation

Claim 2 is different from claim 1. Claim 1 is implicitly limited to a skin electrode, but the claim does not say whether it is the anode or the cathode which is on the skin; it is claim 2 which says that the external means of claim 1 is the anode, with the internal electrode being the cathode. The doctrine of claim differentiation has been satisfied.

Moreover, claim 4 does nothing more than say that the cathode is positionable within the fracture or defect. If claim 1 inherently defined the cathode as the internal means, claim 4 would be nothing but a repetition of that portion of claim 1, contrary to the doctrine of claim differentiation. D. M. I. v. Deere & Co., 755 F.2d 1570, 1575 (Fed Cir.

1985); Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 770 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026.

Invalidity

A. 35 U.S.C. Sec. 112

If the word avoid in claim 1 means minimize fibrous tissue formation, as plaintiff claims, there is no infringement because the OSTEOSTIM causes the development of fibrous tissue around the anode, which is not insignificant, and which creates difficulty when explanting the device. On all models, except the original S-12, the anode is a platinum patch on the titanium case. When first implanted, the 20-microampere current splits about evenly between the platinum and titanium materials. As the weeks go by, an oxide layer builds up on the titanium and more and more of the total current flows through the platinum patch. But even after 10 weeks, 4 microamperes

still flow through the titanium case. So the titanium case functions as part of the anode structure. The fibrous tissue layer which forms around the case/anode of the OSTEOSTIM is not minimal. It is the equivalent of 8 sheets of yellow paper. Thus, the OSTEOSTIM does not minimize fibrous tissue in the "other areas" called for by the claim. The OSTEOSTlM does not, however, develop fibrinoid necrosis. Accordingly, to find infringement, the Brighton patent must be read to minimize fibrinoid necrosis formation from the electrical current.

The re-phrasing of claim 1 to the broad language now under consideration has evolved during the progression of this lawsuit. In the agreed pre-trial statement submitted to this court on January 17, 1986, the plaintiff's counsel submitted this language:

> Plaintiffs further note that claim 1 calls for <u>selecting</u> a <u>current level</u> within a predetermined range so as to promote bone formation in other areas of the living being. This limitation merely refers to the current level used, not where the anode is placed.

Pretrial Statement, pp. 5-6.

Shortly before trial, Dr. Brighton and plaintiff's counsel first informed the defendants' counsel that it was fibrinoid necrosis that was to be minimized in a "trade-off" in selecting the specific value of current to be used within the "window" of 5-20 microamperes. The defendants filed a motion in limine to exclude testimony in support of the contention that the "avoid fibrous tissue formation" phrase in the patent should be interpreted as "avoid fibrinoid necrosis formation", claiming surprise and bad faith from plaintiff's late change of position. This court denied that motion. Upon consideraticn of all the evidence,

it is apparent that this rewrite was required to make a tenable claim of infringement. It is this court's finding that the suggested language of interpretation is a litigation claim; not a patent claim. To accept this argument, this court would have to find that the Navy lawyers made a mistake in writing the language of claim 1. That is too much to ask. Fibrous tissue is living tissue. Fibrinoid necrosis is dead tissue. Anyone with minimum skill in the art would avoid confusing the terms. Moreover, this court has no power to correct a mistake in the language of the claim. Super Products Corp. v. D P Way Corp., 546 F.2d 748, 756 (7th Cir. 1976) ("If the claim does not fairly reflect the invention he seeks to protect, the courts are without power to rewrite the claims even though his invention might

have justified patent protection, . . ."). If claim 1 were to be given the broad meaning which plaintiff asserts, then the patent would be invalid for a failure to comply with the specification requirements of 35 U.S.C. Sec. 112. The plaintiff's reading of claim 1 would make it impossible to determine when sufficient minimization takes place to determine what current range is involved. More importantly, the patent refers only to electrodes made of stainless steel, and it is for that material that the 5-20 microampere range is specified. That range was developed in a dose response experiment with rabbits, described in the patent. The predetermined current range referred to in claim 1 of the Brighton patent will be different for different cathode materials. Dr. Brighton did later studies of platinum electrodes and

determined that the optimum range of current for a platinum cathode is 2-5 microamperes. The patent does not contain an adequate description of the methodology for a dose response study of this type. The plaintiff contends that those of ordinary skill in the art would be able to perform dose response studies for different cathode materials.

A dose response study typically costs about $40,000 to $50,000 to perform and requires six to twelve months. It may involve four disciplines: an electrical engineer, a surgeon, a biomechanic and a biologist. The patent does not describe how to conduct such a study and, accordingly, an undue amount of experimentation is required. Indeed, Dr. Brighton admitted in his testimony that only those who were expert in the field and actually working with bone, doing

electrical stimulation experiments, such as Bassett and Lavine, would know how to conduct a dose response study to determine the appropriate current to be used with other materials as electrodes. Additionally, while the patent refers to 10 microamperes as the preferred constant current for stainless steel electrodes, Dr. Brighton testified that his experiments showed the maximum amount of fibrous tissue formed at 10 microamperes. Given the breadth of the claims made in the plaintiff's arguments, the patent does not tell a person reasonably skilled in the art how to make and use this invention because it fails to teach how to select a level of current to promote bone formation and avoid fibrous tissue and fibrinoid necrosis formation from such current.

B. Obviousness and Anticipation: 35 U.S.C. Secs. 103, 102

The defendants contend that the '841 patent is invalid for obviousness under 35 U.S.C. Sec. 103, and anticipation under 35 U.S.C. Sec. 102. In determining these issues, the court will limit the patent to an external anode.

The principal prior art involved in this aspect of the dispute is the 1964 Nature article [Exhibit 3], the Friedenberg 1968 article [Exhibit 4], and the Kraus patent [Exhibit 17]. The Shamos and Lavine article [Exhibit D-6] is also asserted. It is this collection of prior art which caused the Navy attorneys to emphasize the skin anode in argument which, in turn, has caused this court to limit the claims of the patent. With that limitation to an external anode, this court essentially agrees with the Examiner and the Patent Office on the

validity of the Brighton patent.

In the 1964 Nature article, Dr. Bassett described an experiment in which direct current was applied to the medullary canals of dog bones to study osteogenesis. The device disclosed in the article consisted of a battery and a resistor encapsulated in an epoxy-coated case. Two prongs, which served as the anode and cathode, protruded from the case at a distance of 13 millimeters from each other. The anode and cathode were inserted tightly through two holes drilled in the cortex, or outer wall, of the bone and projected into the medullary canal.

Depending upon the resistor used with the battery, these devices could deliver a current of 1, 10 or 100 microamperes before implantation into the animal. Upon implantation, the current fell rapidly during the first 30 minutes

and then appeared to level off. The 100 microampere battery pack fell to a value of about 3 microamperes. The 10 microampere battery pack fell to about 2 microamperes, and the 1 microampere pack fell to about 0.7 microamperes. Of these packs, the 10 and 100 microampere packs produced more bone around the cathode than inactive control electrodes, while the 1 microampere pack was no more effective than the control. However, bone production reached a peak within 14 days and did not increase thereafter. Dr. Bassett concluded that "under the influence of low level, direct electrical currents, bone formation mechanisms are affected in some way that depends upon the polarity of the applied current, to produce new bone growth preferentially in regions of relative electronegativity." Exhibit 3, p. 654.

The "1968 Friedenberg article," written by Dr. Friedenberg and Dr. Kohanim, is entitled "The Effect of Direct Current on Bone" and appeared in the July 1968 issue of Surgery, Gynecology & Obstetrics. Exhibit 4. The experiment reported in this article was directed toward determining if applying direct current to the tibia bone of an immature rabbit could accelerate the growth of that bone, or lengthen it. A passive current source consisting of a battery and a resistor was used to deliver a current to electrodes inserted into holes drilled into the middle of the epiphysis and the metaphysis. In addition, electrodes were inserted into holes drilled near the tibial tubercule, a relatively less dense part of the tibia near its upper portion, to investigate the effect of current on bone tissue near the electrodes.

The current delivered initially was between 7 and 13.5 microamperes but gradually declined during the experiment. The results showed no significant increase in the length of the bone and destruction of tissue around the anode. Bone formation around the cathode was minimal, consisting of sparse intramedullary trabeculae. The article stated that a "controlled system is needed to deliver a constant current during a prolonged period of time to assess what is the most effective current and what is a destructive current." Exhibit 4, p. 102.

The Assimacopoulous article is entitled "Wound Healing Promotion by the Use of Negative Electric Current." Exhibit 5. It reports the use of approximately 100 microampere currents applied to a wound on the skin of an animal to accelerate the formation of

fibrous tissue to heal the wound.

While this prior art revealed what may be considered the essential components of the Brighton patent, there was doubt that enough bone could be formed to make electrically-induced osteogenesis clinically useful in the treatment of fractures and bone defects.

U.S. Patent No. 3,745,995 issued to Werner Kraus (the "Kraus patent") on July 17, 1973, based on an application filed in the United States on April 9, 1970. Exhibit 17. The Kraus patent discloses an AC, or alternating current, bone growth stimulator which contains two surface plates on the outside of the fracture, a set of electrodes which extend through screws into the medullary canal and another set of electrodes which enter the fracture site. The apparatus also forms a splint for the fracture.

While the Kraus patent does show a

pair of electrodes in a fracture site, it does not suggest that these electrodes could be used without the surface plates and intermedullary electrodes disclosed in that patent. Nor does the Kraus patent suggest that these electrodes should be cathodes if direct current rather than alternating current were used. As of February, 1971, when the Brighton invention was made, those skilled in the art recognized the use of alternating current as distinct from direct current. Some research teams experimented with both DC and AC systems. But, it was not apparent that the electrical parameters used in an AC system could be transferred to a DC system. The manner in which AC and DC systems operated were thought to be distinct from each other.

The claimed invention would not have

been obvious to one of ordinary skill in the art at the time Dr. Brighton and his co-workers made their invention. The defendants argue that it would have been obvious to modify the device disclosed in the Nature article to include a power source with self-adjusting, active circuitry to supply a constant current in a range sufficient to heal a fracture, given the suggestion in the 1968 Friedenberg article that a controlled source was needed to permit experimentation with constant current. However, the suggestion that a controlled source was needed appears to have meant different things to the various workers in the field. For example, even after Dr. Brighton and his co-workers made their invention, the Lavine group was still using a power source with a battery and a variable resistor without any compensating circuitry.

These articles show that the Lavine team, while it realized the need to control the current delivered to the defect site, never recognized the desirability of using active circuitry to maintain a constant current despite changes in load and they chose not to use an internal cathode at the fracture site, but rather, tried to provide current flow across the fracture site by using two electrodes squeeze-fit into drill holes on either side of the fracture site.

The Friedenberg article, read in its entirety, describes a failed experiment in which the authors tried unsuccessfully to stimulate the growth plate to lengthen the bone rather than expedite healing of a fracture. The fact that this work was a failure makes it highly uncertain that one of ordinary skill at the time would have seized on the one sentence in that

article that defendant emphasizes. Neither the 1964 Nature article nor the 1968 Friedenberg article was concerned with the use of electrically induced osteogenesis to heal a fracture. Rather, they were directed to attempts to study whether electricity could produce bone formation rather than whether electricity could produce sufficient bone to expedite the healing of a fracture. Moreover, when O'Connor attempted to apply the teachings of the 1964 Nature article to the problem of fracture his results were completely negative and disappointing. O'Connor concluded that "[a]lthough our results agree in general with those of Bassett, Pawluk and Becker, the differences between our findings and theirs emphasize the need for caution in clinical applications for there seems to be considerable biological variation in the response of bone to electric current even

within a single species." Exhibit 13, pp. 162-163.

Defendants further seek to combine the disclosures of the 1964 Nature article and the 1968 Friedenberg article with the electrodes placed in the fracture site in the Kraus patent. However, the Kraus patent discloses several electrodes without suggesting that the electrodes in the fracture site can be separated from the rest of the device and used in a DC system. While some of the same people experimented with both AC and DC devices in studying electrically induced osteogenesis, they did not apply the electrical features of AC devices to DC devices, or vice versa. The evidence does not show that one of ordinary skill in the art would have found it obvious to adapt the electrode at the fracture site in the Kraus patent to form a cathode in a DC

system.

Since it would not have been obvious to have made the invention defined in claim 1, which requires a self-adjusting constant current source and an internal cathode at the fracture site, it would not have been obvious to make the inventions defined in dependent claims 3, 4 and 5.

Another set of factors relevant to a determination of invalidity for obviousness under section 103, is objective evidence of nonobviousness, including long-felt need and commercial success. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). Dr. Brighton emphasized that the Zimmer device healed nonunions in a clinically practical and reproducible manner. Prior to the Brighton invention nonunions were treated by bone grafting. If bone grafting proved unsuccessful, then amputation was performed. There is

also some merit to the plaintiff's argument that the gross sales of the Zimmer device suggest that it is a commercial success, another indication of nonobviousness. See, W.L. Gore & Associates, Inc., v. Garlock, Inc., 721 F.2d 1540, 1555 (Fed. Cir. 1983), cert. denied, 469 U.S. 851.

C. Fraud or Inequitable Conduct in the Patent Office

The defendants contend that the patent should be invalidated because the Navy attorneys committed fraud, or at least, inequitable conduct in the arguments made before the Examiner. This contention is based principally on the statements concerning the reasons for distinguishing the 1964 Nature article and the importance of the constant current findings by the inventors. More particularly, the attorneys are accused of misrepresenting the 1964 Nature arti-

cle as not being related to healing, but only to osteogenesis, and the principal inventor, Dr. Karl Brighton, testified both in deposition and at trial that the constant current may not be as significant as the current level in the healing process. This court has carefully reviewed the prosecution history, the testimony of Dr. Brighton in deposition and at trial, the deposition testimony of Dr. Friedenberg, and the arguments made in the defendants' briefs. What appears is that the patent was ineptly argued by counsel who apparently had limited understanding of the subject matter and inadequate communication with Dr. Brighton and the other inventors. The plaintiff has already suffered the adverse consequences of the use of a prosecution argument to limit the scope of claim 1. The evidence is insufficient to support the defend-

ants' claims that there was any intent to misrepresent or mislead the Patent Office. The inadequacy of counsel is not equated with fraud or inequitable conduct.

D. Misjoinder of Inventors

The defendants also claim that William Redka should not have been named as a co-inventor of the Brighton patent because his only contribution was the design of the self-adjusting constant current source disclosed in the patent, and which is the subject of claims 6 through 10, not the claims in suit. Under 35 U.S.C. Sec. 116, when an invention is made by two or more persons jointly they must join in the applica-

tion.[1] It is not clear that there is any requirement that all co-inventors must have combined their efforts to each claim in the patent. SAB Industri AB v. Bendix Corp., 199 U.S.P.Q. 95 (E.D.Va. 1978). If that is the law, it is this court's view that the circuitry design made by Redka is sufficiently related to the patent in its entirety to justify the inclusion of his name as as inventor.

At any rate, if there were misjoinder, it is irrelevant to invalidity in this case because the plaintiff has shown an absence of deceptive intention under 35 U.S.C. Sec. 256. Dr. Brighton testified that he regarded Redka as an inventor, and

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[1] This section was amended by Pub. L. No. 98-622, effective November 8, 1984. The amendment expressly provides that the co-inventors need not make a contribution to the subject matter of every claim of the patent.

Redka's particular participation was specified in an affidavit filed with the Patent Office on May 3, 1974. Redka, along with Dr. Brighton, was a University of Pennsylvania employee and his work was part of the performance of the contract with the Office of Naval Research. Naming Redka as a co-inventor had no effect on the ownership of the patent and could confer no financial benefit on Redka. The burden of proof on the issue of deceptive intent is a negative burden on the plaintiff. There is, however, nothing to suggest any motivation to mislead the Patent Office on this point. A finding of deceptive intent would be purely speculative. Under all of the circumstances, this court is persuaded that the naming of Redka as a co-inventor was done either because the attorneys prosecuting the patent believed that his contribution could be considered as a part of all of

the claims of the patent or as a result of a failure of those attorneys to appreciate the requirement that the participation of co-inventors must be with respect to the entire invention. Because the court is persuaded that there was no deceptive intent, the patent should be corrected on notice and hearing pursuant to 35 U.S.C. Sec. 256.

Exceptionality

The final issue is the defendants' claim of entitlement to an award of attorneys' fees under 35 U.S.C. Sec. 285. Section 285 permits a court to award attorneys' fees to the prevailing party only in exceptional cases. While this court has agreed with the defendants' contentions that there is no literal infringement; that infringement under the doctrine of equivalents has not been sustained because the prosecution history

limits the claims to the use of a skin anode, and that if claim 1 is rewritten as the plaintiff contends, it would be invalid, the court is not persuaded that this infringement action has been prosecuted in bad faith. Moreover, the defendants did not prevail on their affirmative defense and counterclaim of invalidity. The plaintiff's position did receive support from expert witnesses and, indeed, this case has been difficult for this court to decide. Accordingly, there is no basis for finding that this is an exceptional case, and the defendants' claim for attorney's fees is denied.

Upon the foregoing, it is

ORDERED, that judgment shall enter for the defendants on the plaintiff's claims of patent infringement and for the plaintiff on the defendants' affirmative defenses and counterclaims of patent

invalidity, and it is

FURTHER ORDERED, that all parties shall show cause in writing to be filed on or before Monday, April 27, 1987 why this court should not direct the entry of final judgment on these claims and counterclaims pursuant to F. R. Civ. P. 54(b).

Dated: April 7, 1987

BY THE COURT:

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Richard P. Matsch, Judge

Supreme Court, U.S.
FILED
APR 12, 1989
JOSEPH F. SPANIOL, JR.
CLERK

No. 88-1397

In the Supreme Court of the United States

OCTOBER TERM, 1988

TELECTRONICS, INC. AND BGS MEDICAL, INC., PETITIONERS

v.

UNITED STATES OF AMERICA AND ZIMMER, INC.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTION PRESENTED

Whether, after the court of appeals construed the patent more broadly than the district court in this patent infringement suit, it should have remanded the case for a determination of whether the plaintiff's patent was invalid for obviousness.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-38a) is reported at 857 F.2d 778. The opinion of the district court (Pet. App. 1d-60d) is reported at 658 F. Supp. 579.

JURISDICTION

The judgment of the court of appeals (Pet. App. 1c-2c) was entered on September 22, 1988, and a petition for rehearing (Pet. App. 1b-2b) was denied on November 23, 1988. The petition for a writ of certiorari was filed on February 21, 1989. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

The government brought this action against petitioners alleging that they were infringing its U.S. Patent No. 3,842,841 (the Brighton patent). The patent describes a device to expedite the healing of fractures and other bone defects by stimulating bone growth using a small amount of direct electrical current (Pet. App. 1d-3d). The Brighton patent resulted from work under a Navy contract by University of Pennsylvania employees, who assigned the patent to the government, which in turn granted respondent Zimmer, Inc. an exclusive license (Pet. App. 3a).

Zimmer and petitioner Telectronics manufacture the only direct current bone growth stimulators approved for use in the United States (Pet. App. 4d). In both the Zimmer and Telectronics devices, the cathode (*i.e.*, the negative electrode) is placed internally in the bone at the site of the fracture (Pet. App. 4d, 9d-10d). In the Zimmer device, the anode (*i.e.*, the positive electrode) and power pack are placed on the skin of the patient, but in the Telectronics device, the anode and power pack are implanted under the patient's skin (Pet. App. 9d-10d).

Following a trial, the district court held that the critical question was whether claim 1 of the Brighton patent[1] was

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[1] Claim 1 states (Pet. App. 7d-8d):

1. A system for expediting the healing of bone fractures and defects in a living being comprising:

constant current source means for providing a constant value of current despite changes in load;

means for connecting said constant current means to the living being, such connection acting to produce current flow into said fracture or defect,

said connecting means including further means for application internally of said living being at the fracture or defect site,

said constant current being a selected value within a predetermined microampere range so as to promote bone formation at the

limited to a bone growth stimulator having an anode positioned on the patient's skin (Pet. App. 10d). The district court concluded that the claim was so limited, because the final paragraph of claim 1 required the avoidance of fibrous tissue around the anode and the case of the stimulator (Pet. App. 12d). When the anode and case are implanted, as in the Telectronics device, fibrous tissue builds up to a thickness of about 1 millimeter (Pet. App. 10d, 35d). On this basis, the district court concluded that the Telectronics device did not infringe the Brighton patent (Pet. App. 12d).

The district court also held that the contested claims of the Brighton patent were valid under 35 U.S.C. 103 and 112.[2] In discussing validity under Section 103, which requires that the invention not have been obvious to one of ordinary skill in the applicable art, the court reviewed the prior art in light of the court's limitation of the patent claims to a device with an external anode (Pet. App. 41d-53d). Irrespective of this limitation, however, the court concluded that two features of the patent claims were not obvious: use of a self-adjusting constant current

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fracture or bone defect site and avoid fibrous tissue formation in other areas of the living being.

[2] Section 103 provides in relevant part:

> A patent may not be obtained * * * if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. * * *.

Section 112 provides in relevant part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same * * *.

source and a cathode designed for placement in the fracture site (Pet. App. 47d-52d). The court also applied the external anode limitation in concluding that the claims were valid under Section 112, which requires that the patent's specifications be sufficiently full and clear "to enable any person skilled in the art * * * to make and use" the invention. 35 U.S.C. 112 (Pet. App. 34d-40d). Finally, the district court denied petitioners' claim for attorneys' fees (Pet. App. 58d-59d).

The government appealed the holding of noninfringement to the Federal Circuit. Petitioners cross-appealed only on whether the patent was invalid under Section 112 and on whether attorneys' fees should have been awarded (Pet. App. 2a).

The court of appeals reversed on the government's noninfringement appeal and affirmed on petitioners' cross-appeal issues (Pet. App. 1a-38a). The court held that "the plain meaning of the disputed language" in claim 1[3] "is only that current-related fibrous tissue formation is to be avoided" (Pet. App. 12a). As the court explained, "[n]othing in this language relates to fibrous tissue that may be formed from implantation of an anode" (*ibid.*). Finding the claim's literal meaning supported by other accepted aids for construing patent claims, such as the patent's specifications[4] and its prosecution history, the court held that the Brighton patent was sufficiently broad to cover anodes placed either on the skin or internally. The

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[3] Specifically, that language is "constant current being a selected value * * * so as to * * * avoid fibrous tissue formation * * * " (Pet. App. 8d).

[4] Although fibrous tissue can result either from a reaction to a foreign body or from the application of electrical current (Pet. App. 11d), the Brighton patent specification discusses only the increase or decrease in fibrous tissue that is formed with varying currents. The specification thus supports the plain meaning of the claim language at issue (Pet. App. 13a).

court accordingly concluded that the Telectronics device infringed that patent (Pet. App. 12a-27a).

The Federal Circuit then rejected petitioners' claim that the Brighton patent was invalid. The court held that the patent sufficiently described the invention to enable a person reasonably skilled in the art to make and use it as required by 35 U.S.C. 112 (Pet. App. 27a-38a). The court rejected petitioners' argument that the specifications were inadequate because they only described the range of electrical current for stainless steel electrodes, not for those of other metals (*ibid.*). In view of its holdings against petitioners on both infringement and validity, the court did not reach their claim for attorneys' fees (Pet. App. 38a).

ARGUMENT

The decision below is correct and, as petitioners concede (Pet. 18), does not conflict with the decision of any other circuit. Accordingly, further review of petitioners' fact specific claim is not warranted.

Petitioners contend (Pet. 13-15) that, after it had construed claim 1 more broadly than the district court, the Federal Circuit should have remanded the case for a new determination of whether the Brighton patent was invalid for obviousness.[5] There is a serious question as to whether

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[5] Petitioners also argue (Pet. 19-22) that the Federal Circuit did not address their claim that there was no infringement of the Brighton patent because the Telectronics device did not avoid the formation of fibrous tissue. The Federal Circuit, however, held that the "plain meaning of the disputed language [of claim 1 of the Brighton patent] is only that current-related fibrous tissue formation is to be avoided" (Pet. App. 12a). Thus, fibrous tissue formation caused by the implantation of the anode in the Telectronics device (see Pet. App. 11d) plainly cannot establish non-infringement. Moreover, petitioners not only failed to dispute on appeal the district court's statement that construction of claim 1 was the crucial issue regarding infringement, but

petitioners preserved the obviousness issue in the court of appeals and hence in this Court. While petitioners asserted in the district court that the Brighton patent was invalid both for obviousness under 35 U.S.C. 103 and for lack of enablement under 35 U.S.C. 112, in the Federal Circuit they argued only the enablement point, a point they do not raise in the petition. They expressly declined to brief the obviousness point. Cross-Appellants' Br. 10 & n.*. To be sure, their brief contained one sentence stating, "Should this Court reverse on the *non-infringement* ruling, then a remand would be necessary to allow the District Court to reconsider *validity* based on the prior art * * *." *Id.* at 10 (emphasis in original). Nowhere in their brief,[6] however, did petitioners attempt to demonstrate that the district court's finding on the obviousness issue should be different if claim 1 were construed more broadly to include both external and internal anodes. Absent extraordinary circumstances, which are not present here, this Court does not consider arguments that were not properly raised in the court of appeals. See *e.g.*, *EEOC* v. *FLRA*, 476 U.S. 19, 24 (1986); *Neely* v. *Eby Constr. Co.*, 386 U.S. 317, 330 (1967).

In any event, petitioners' claim is without merit. As the district court recognized, there are two principal differences between the invention claimed in the Brighton patent and the prior art: the use of self-adjusting circuitry to maintain a constant current and the use of a cathode de-

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they even conceded that the infringement issue "revolve[d] around" whether the claims were limited to a device with an external anode. Cross-Appellants' Br. 7.

[6] Petitioners did attempt to develop such an argument in their petition for rehearing, but the court below acted within its discretion by refusing to consider a new argument raised only after its decision. See *Marion Steam Shovel Co.* v. *Bertino*, 82 F.2d 945 (8th Cir.), cert. denied, 299 U.S. 556 (1936).

signed for placement in the fracture site (Pet. App. 47d-52d). Neither distinction is at all relevant to whether the anode is external or internal. Thus, the Federal Circuit's disagreement with the district court as to whether claim 1 covered both placements of the anode provided no basis for remanding for a redetermination of the district court's obviousness determination.[7]

Also without merit is petitioners' claim (Pet. 15-18) that the failure of the Federal Circuit to remand conflicts with its earlier decision in *Perkin-Elmer Corp.* v. *Westinghouse Elec. Corp.*, 822 F.2d 1528 (1987).[8] The dictum in *Perkin-Elmer* on which petitioners rely reflects simply that panel's reaction to the particular facts before it.[9] When Perkin-Elmer sued Westinghouse for patent infringement, Westinghouse conceded that the patent was valid if narrowly construed. So construed, the district court held that the patent was valid but not infringed. On Perkin-Elmer's

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[7] This Court discussed the obviousness standard in *Graham* v. *John Deere Co.*, 383 U.S. 1 (1966). It recognized that "[w]hile the ultimate question of patent validity is one of law," the obviousness determination "lends itself to several basic factual inquiries," *i.e.*, "the scope and content of the prior art," "differences between the prior art and the claims at issue," and "the level of ordinary skill in the pertinent art" (*id.* at 17). See also *Dennison Mfg. Co.* v. *Panduit Corp.*, 475 U.S. 809 (1986).

[8] Congress established the Federal Circuit as the court of appeals having exclusive jurisdiction to resolve patent issues of the kind presented here. 28 U.S.C. 1295(a)(1). Contrary to petitioners' suggestion (Pet. 18), this fact does not justify a departure from this Court's usual rule that intra-circuit conflicts are for the circuit involved, not this Court, to resolve. *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957).

[9] The fact that, as petitioners observe (Pet. 16-17), two of the judges on the instant panel also served on the *Perkin-Elmer* panel strongly supports this conclusion, rather than petitioners' assumption (Pet. 17) that they "decided to simply ignore their own precedent."

appeal, the Federal Circuit affirmed the finding of non-infringement, which was the only issue on the appeal. The court then stated that it was unnecessary for it to review the district court's interpretation of the patent claims. It commented in passing that if it had done so and reversed, it would remand; the "[v]alidity of the properly construed claim would be a potential issue on such a remand." *Id.* at 1530 n.4. Even assuming that the obiter dicta in *Perkin-Elmer* should be given the weight of a holding, that was not a case like the instant one, in which the district court had already found differences between the prior art and the invention that were distinct from the disputed construction of the claim.

In any event, *SmithKline Diagnostics, Inc.* v. *Helena Laboratories Corp.*, 859 F.2d 878 (1988), refutes petitioners' claim that the *Perkin-Elmer* dictum expresses a general Federal Circuit practice requiring a remand for the consideration of obviousness. In *SmithKline Diagnostics,* the Federal Circuit construed a disputed claim more broadly than the district court. It then reviewed the obviousness issue and affirmed the holding of validity based, as here, upon the district court's factual findings which led to a legal conclusion of nonobviousness. *Id.* at 886.

CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

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